8EHQ-1095-13538

Lilly

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-2000

ORIGINAL

October 23, 1995

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Contains No CBI

Document Processing Center (TS-790)
Attn: 8(e) Coordinator
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

RECEIVED
OPPT CBIC
95 OCT 26 PM 3:24

Dear Sir/Madam;

Pursuant to Section 8(e) of the Toxic Substances Control Act, Eli Lilly & Company ("Lilly") is submitting the following information regarding an adverse reaction following human ingestion of a TSCA-regulated chemical substance.

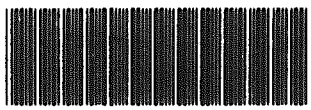
Chemical Substance: monensin sodium

CAS Number: 22373-78-0

Source of Information:

RECEIVED
OPPT NCIC
95 NOV -8 PM 8:04

The information in this submittal was reported to Lilly by letter dated October 4, 1995 by a foreign affiliate, which learned of the incident from a foreign customer of the affiliate. The foreign



customer purchases monensin sodium from the Lilly foreign affiliate, and Lilly manufactures monensin sodium in the United States. Information regarding the incident was reported orally to the affiliate, and neither Lilly nor its affiliate have any first-hand knowledge or documentation regarding the event that is the subject of this submittal.

Adverse Reaction to Ingestion:

Two employees of a foreign customer of a foreign Lilly affiliate each purposefully orally ingested approximately 10 grams of monensin sodium mixed with water. Within a few hours, both became very sick. One vomited. Both were taken to a hospital and treated with intoxication medication support (i.e., liquids). One of them died 10 days after consumption due to severe kidney problems. The other (who had vomited) recovered, though he still felt light muscle torpidity at 10 days after the incident.

The severity of this reaction is not surprising. Monensin is a fermentation product in the ionophore class of compounds. The toxicology of monensin sodium has been thoroughly characterized by studies in laboratory animals. The median lethal dose of monensin sodium in rats is 34 mg/kg.

Extent of Risk Posed by Chemical Substance:

This incident occurred as a result of a blatant and highly improbable product misuse. Monensin sodium's only medicinal/consumptive use is in FDA-regulated animal health products. Lilly does not sell or market it for human use in any form, and its product labels warn against human consumption. Lilly understands that the workers consumed the monensin in an attempt at self-medication for venereal disease. (The plant at which they worked apparently also uses penicillin in its operations, and the two substances are apparently similar in appearance in the form in which they were used at the facility.)

Please contact me if you require any further information regarding this submittal.

Sincerely,

ELI LILLY & COMPANY

Donald R. Brannon
Advisor, Environmental Affairs
(317)-276-4672

cmp